IN THE COURT OF COMMON PLEAS
MONTGOMERY COUNTY, OHIO

THE MONTGOMERY COUNTY BOARD OF COUNTY COMMISSIONERS
451 West Third Street
Dayton, Ohio 45422;
THE STATE OF OHIO *EX REL.*
MATHIAS H.HECK, JR., PROSECUTING ATTORNEY
301 West Third Street
Dayton, Ohio 45422

Plaintiffs,

vs.

CARDINAL HEALTH, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

MCKESSON CORPORATION
c/o Corporation Service Company
50 West Broad Street
Suite 1330
Columbus, OH 43215

And

Case No.:

Judge

Complaint

(Jury Demand Endorsed Hereon)

AMERISOURCEBERGEN DRUG
CORPORATION
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

AND

WALGREENS CORPORATION
c/o Corporation Service Company
50 West Broad Street
Suite 1330
Columbus, OH 43215

And

JANE DOES 1 – 50

Defendants.

PRELIMINARY STATEMENT

1. Plaintiff Board of County Commissioners of Montgomery County, Ohio by and through the Montgomery County Prosecutor's Office (the "County") brings this action to redress AmerisourceBergen Drug Corporation's, Cardinal Health, Inc.'s, McKesson Corporation d/b/a McKesson Drug Company's, and Walgreen Co.'s (together "Defendants") unfettered and unlawful distribution of opioids into the County.

2. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[1] Consequently, the prescribing of opioids was sharply constrained.

3. In the mid-1990s, however, pharmaceutical companies (which the County is suing in a separate action) aggressively and deceptively marketed opioids for common chronic conditions like back pain, migraines, and arthritis. By the mid-2000s, chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—became widespread and the use of opioids skyrocketed. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S.

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

4. Taking advantage of this mass market, Defendants flooded many communities with opioids, without conducting the due diligence required by law to prevent the diversion of opioids to an illicit market for these drugs that predictably developed, and that Defendants helped to create, expand, and maintain.

5. All told, Montgomery County, with an average population from 2010 to 2017 of approximately 535,000, received a total of **310,583,228** retail doses of opioid analgesics during the same time frame, with a high of 42,280,396 in 2012. This amounted to 149 doses per opioid patient, 18 doses per person, and with an average of 12% of the population receiving an opioid over this time period. In each of these measures, Montgomery County exceeded the state averages of 148 doses per patient, 16 doses per person, and 11% of the population receiving opioids, an unfortunately already high baseline.

6. According to data from the CDC, Montgomery County had more opioid prescriptions than people each year from 2006 to 2015. The prescription rate remained high — 92.9 opioid prescriptions for every 100 people (including children) in the County — in 2016.

7. Nationally, Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation d/b/a McKesson Drug Company account for approximately 90% of all revenues from prescription drug distribution in the U.S. Known colloquially as the "Big Three," these Defendants dominate the wholesale drug distribution market, including in the County. Walgreens Boots Alliance, Inc. a/k/a Walgreen Co. is also a significant wholesale distributor of prescription opioids.

8. Defendants are paid to securely deliver opioids made by the various manufacturers and are the closest link to pharmacies throughout the country. As registered distributors of controlled substances, Defendants are placed in a position of special trust and responsibility.

Because of their direct relationship with pharmacies in the supply chain, they are uniquely capable of determining whether a pharmacy is facilitating the diversion of prescription opioids.

9. Defendants have common law and statutory duties to provide adequate controls against diversion. Each Defendant is legally mandated to monitor for, report, and reject suspicious orders of controlled substances into the County. Such orders include, for example, orders of opioids that exceed reasonable volume, are of an unusual frequency, or that raise other red flags. Yet, Defendants shipped orders that they knew or should have known were being diverted or used other than for legitimate medical purposes.

10. Sales and distribution data available to Defendants, as well as their own observations, would, or should, have put them on notice of potential diversion. Yet, upon information and belief, Defendants consistently failed to report or suspend these illicit orders, deepening the crisis of opioid abuse, addiction, and death in the County. Defendants had financial incentives to continue to supply opioids to pill mills (doctors, clinics, or pharmacies that prescribe or dispense opioids inappropriately or for non-medical reasons) because they may entitle them to volume-based rebates and discounts that they may then leverage to further increase their sales volumes and profits. Defendants have supplied opioids in quantities that they knew or should have known exceeded any legitimate market for opioids—even the wider market for chronic pain—and, upon information and belief, ignored red flags of suspicious orders of these drugs in Montgomery County.

11. As a direct and foreseeable result of Defendants' conduct, the nation and Montgomery County are now swept up in what the Centers for Disease Control and Prevention ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an

"urgent health crisis."[2] In 2015, an estimated 2 million Americans were addicted to prescription opioids and 591,000 to heroin. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend.

12. The careless, even reckless distribution of opioids into the County correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. Prescription opioids at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

13. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. And, the link between prescription narcotic painkiller abuse and subsequent and/or simultaneous heroin abuse continues to grow. Across the country, **80% of recent heroin users** have previously used prescription opioids non-medically. As the American Society of Addiction Medicine has explained, four out of five new heroin users started with prescription painkillers. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease Control and

[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm;. Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

14. This transition became even more dangerous in recent years, as increasingly powerful synthetic opiates began entering communities. People who use heroin may not know when it has been combined with fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Ohio communities, including Montgomery County.

15. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old, eclipsing guns or car accidents or accidents. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak. According to Robert Anderson, who oversees death statistics at the CDC, "'I don't think we've ever seen anything like this. Certainly not in modern times.'"[3]

16. Ohio is among the states hardest hit by the opioid epidemic. As a recent report from The Ohio State University summarizes, "[o]pioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio."[4] The rapid rise in overdose deaths in Ohio and the United States as a whole is unprecedented. Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and

[3] Associated Press, *Drug Overdoses Killed 50,000 in U.S., More than Car Crashes*, (Dec. 9, 2016), https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001

[4] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

local governments across the state."[5] Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and a half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

17. Montgomery County is not only no exception to this deadly trend, it has been considered ground zero for the opioid epidemic. In 2017, the media dubbed Montgomery County the "overdose capital of America" after the County recorded the most overdose deaths, per capita, in the United States during the first half of that year. In just six-years, from 2010 to 2016, fatal drug overdoses have claimed the lives of 1,517 people in the County, and 349 people died of opioid overdoses in 2016 alone. In 2017, that number rose to 559 lives lost.

18. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Hundreds of people have been rushed to County emergency rooms or revived by EMS or community members trained to administer Narcan — an antidote to overdose. In the first three months of 2018 alone, the Montgomery County Sheriff's Office's Regional Dispatch Center received 335 calls for drug overdoses. In the month of March, the Dispatch Center consistently received more than 20 of these calls per week. The vast majority with recorded causes involved opiates, whether illicit or prescription.

19. The damage inflicted cuts across ages and generations. Many who have succumbed to overdoses have overdosed more than once. Those who survive are often not alone at the time. Family members, including young children, have watched their loved ones lose consciousness or

[5] *Id.*

die. Young children, including toddlers, also have been the direct victims of overdoses themselves after coming into contact with opiates.

20. Children are being displaced from their homes and raised by relatives or placed in the County's care due to parents' addiction. Others lose the chance to go home. Unable to be discharged from the hospital with their mothers, babies born addicted to opioids due to prenatal exposure are being placed in the care of the County or local citizens or non-profits who do their best comfort them through the pain of withdrawal.

21. This human tragedy cannot be calculated or compensated. But the financial burden to the County is staggering. The County has expanded its own services and worked collaboratively with the community to confront this public health epidemic. Narcan administration has saved the lives of hundreds of its residents. Expanded addiction treatment services, recovery housing, and innovative programs have sought to help people heal. The County would further expand these efforts, but has only so much funding, which the demands of this unprecedented epidemic have so overwhelmed. The County is also faced with increased costs of drug crimes and other public services because of the opioid epidemic. Meanwhile, Defendants have not changed their ways or corrected their past misconduct, but instead are continuing to fuel the crisis.

22. Defendants' conduct has violated, and continues to violate, the Ohio Corrupt Practices Act ("OCPA"), R.C. § 2923.31 *et seq.*, and R.C. § 2307.60, which provides civil liability for injuring another through criminal acts. Additionally, Defendants' conduct constitutes a public nuisance, civil conspiracy, negligence, and unjust enrichment.

23. Accordingly, the County brings this action to hold Defendants accountable for their conduct and seeks abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unlawful practices.

PARTIES

1. Plaintiffs

24. The County of Montgomery, Ohio ("the County") is a County organized under the laws of the State of Ohio, and is the fifth most populous county in, Ohio. The County has its seat of government in Dayton, Ohio. The Montgomery County Prosecutor's Office is located at 301 West Third Street, Dayton, Ohio 45422. The County provides many services for its residents, including public assistance, law enforcement services, criminal justice services, addiction and mental health services, and services for families and children.

25. This action is also brought on behalf of the State of Ohio, by and through Mathias H. Heck, Jr., Prosecuting Attorney, with regard to the claim for statutory public nuisance in the name of the State of Ohio under R.C. §§ 3767.03 and 4729.35.

2. Defendants

26. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1990. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.

27. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco,

California. McKesson has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1996. McKesson operates a warehouse in Washington Court House, Ohio.

28. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio and three other states. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[6]

29. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1988. AmerisourceBergen operates a warehouse in Lockbourne, Ohio. A division of AmerisourceBergen, Besse Medical Services, Inc., operates a warehouse in West Chester, Ohio.

30. Defendant Walgreens Boots Alliance, Inc., also known as Walgreen Co. ("Walgreens"), is a Delaware corporation with its principal place of business in Illinois. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue

[6] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal year 2017.

31. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Ohio.

32. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.

33. For Defendant Jane Does 1 – 50, the County lacks sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The County will amend this Complaint to show their true names when they are ascertained.

34. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

35. This Court has jurisdiction over this matter pursuant to R.C. § 2305.01.

36. This Court has personal jurisdiction over all Defendants under R.C. § 2307.382 because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, causing tortious injury in Ohio and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or deriving substantial

revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

37. The damages sought in this action exceed the amount of the exclusive original jurisdiction of the municipal courts.

38. The venue for this claim is proper in the Court of Common Pleas of Montgomery County under Ohio Civ. R. 3(B)(3), (6), and (7).

A. DEFENDANTS DELIBERATELY DISREGARDED THEIR DUTIES TO REPORT AND TERMINATE SUSPICIOUS ORDERS.

1. Defendants have a duty to report suspicious orders and not to ship those orders unless due diligence disproves their suspicions.

39. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids in Montgomery County and a lucrative opportunity for Defendants, who compounded this harm by failing to maintain effective controls against diversion and instead facilitating the supply of far more opioids that could have been justified to serve that market and supplying opioids they knew or should have known were being abused or diverted. Defendants' failure to investigate, report, and terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

40. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Montgomery County with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that it knew or should have realized were likely being diverted for illicit uses, Defendants breached

their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to the County.

41. Second, each Defendant assumed a duty, when speaking publically about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

42. Third, Defendants violated their statutory obligations under Ohio law, which also incorporates the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. *See* Ohio Administrative Code §§ 4729-9-16(L) and 4729-9-28(I) (mandating that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations").

43. Each of the Defendants was required to obtain a license from the state (as well as to register with the DEA) to distribute Schedule II controlled substances. *See* R.C. §§ 4729.52-53 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. Federal regulations issued under the CSA and incorporated into Ohio law pursuant to Ohio Administrative Code §§ 4729-9-16(L) and 4729-9-28(I) further mandate that, as registrants, distributors "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74(b). Further, Ohio law requires, as a condition of licensure by the State Board of Pharmacy, that a wholesaler assure adequate safeguards to prevent the sale of dangerous drugs other than in accordance with section 4729.51 of the Revised Code." R.C. § 4729.52.

44. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the CSA in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of

distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[7] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

45. The CSA requires distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

46. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled

[7] Statement of Joseph T. Rannazzisi, U.S. House Committee on Energy and Commerce Subcommittee on Health, Improving Predictability and Transparency in DEA and FDA Regulation (April 7, 2014) (quoting H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572), https://www.dea.gov/pr/speeches-testimony/2014t/04072014t.pdf

substances], and the requirement of order forms for all transfers of these drugs."[8] When evaluating production quotas, the DEA was instructed to consider information including trends and rates of net disposal, an applicant's production cycle and current inventory position, total actual or estimated inventories of the class of drug and all substances manufactured from the class, trends in inventory accumulation, and other factors such as changes in the currently accepted medical use of substances, the economic and physical availability of raw materials, yield and sustainability issues, potential disruptions to production, and unforeseen emergencies.

47. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

48. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, ordering the same controlled substance from multiple distributors.

49. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order

[8] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)

alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

50. Under Ohio law, distributors also have a duty to detect, investigate, refuse to fill, and report suspicious orders of opioids. To that end, the Ohio Pharmacy Board requires that drug wholesalers "shall establish and maintain inventories and (records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs," and that, as a minimum requirement of wholesale distribution in this State, "[a] system ***shall be designed and operated to disclose orders*** for controlled substances and other dangerous drugs subject to abuse." Ohio Administrative Code ("O.A.C.")§ 4729-9-16(H) (emphasis added); R.C. § 4729.52 (requiring licensed wholesale distributors to comply with Ohio Board of Pharmacy security regulations); *accord* 21 U.S.C. § 823; 21 C.F.R. 1301.74 (imposing duty to monitor, detect, investigate, refuse to fill, and report suspicious orders under federal law).[9]

51. Ohio regulations further mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the Ohio Board of Pharmacy: "The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered.

[9] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter "2007 Rannazzisi Letter").

Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, ***or*** deviate substantially from established buying patterns." O.A.C.§ 4729-9-16(H)(1)(e) *et seq.* (emphasis added); *see also* O.A.C.§§ 4729-9-12(G) & 4729-9-28(E). Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

52. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All flagged orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which

were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.[10]

53. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors would not fall. Together, these laws and industry guidelines make clear that wholesalers and manufacturers of controlled substances alike possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

54. Further, these laws and industry guidelines make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

55. All Defendants have a duty to, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

2. Defendants understood the importance of their reporting and due diligence obligations.

56. As explained above, the reason for the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[11] Both because wholesale distributors handle such large volumes of

[10] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

[11] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[12]

57. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences. In fact, trade organizations to which Defendants belong have acknowledged that wholesale distributors such as Defendants have been responsible for reporting suspicious orders for more than 40 years.[13] The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Defendants AmerisourceBergen, Cardinal, and McKesson, belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[14] Guidelines established by the HDA also explain

[12] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[13] *See* Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .") (emphasis omitted).

[14] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of

that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[15]

58. The FTC, too, has recognized the unique role of wholesale distributors. Since their inception, Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, these Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with generic manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[15] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

59. As a national pharmacy chain, as well as a distributor, Walgreens has especially deep knowledge of its retail stores' orders, prescriptions, and customers. This is underscored by the fact that Walgreens is able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.

60. The DEA also repeatedly has made clear that Defendants' obligations under federal law, mirrored in and incorporated by Ohio law, *see infra* ¶¶ 42-43 & 50-51, obligate them to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

61. The DEA also, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included Defendants) that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and

general welfare of the American people."[16] The DEA's September 27, 2006 letter also expressly reminded them that registrants, *in addition* to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[17]

62. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[18] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[19]

[16] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[17] *Id.*

[18] 2007 Rannazzisi Letter.

[19] *Id.*

3. Despite repeated admonitions, Defendants have repeatedly violated their reporting and due diligence obligations.

63. Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

64. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

65. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, and McKesson:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

66. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the state CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

67. Walgreens also has been penalized for serious and flagrant violations of the CSA. On February 12, 2012, the DEA issued an Order to Show Cause and Immediate Suspension of Registration against Defendant Walgreens' Jupiter, Florida distribution center, ("Jupiter Center") for failure to maintain effective controls against the diversion of opioids. The DEA found, among other things, that the Jupiter Center failed to conduct adequate due diligence and should have known that the Walgreens pharmacies were dispensing controlled substances, including opioids, for other than legitimate medical purposes.

68. In June 2013, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA at the Jupiter Center and six Walgreens retail pharmacies in Florida, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales. The Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens' "alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."[20]

69. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount. In addition to the monetary payment, the Jupiter, Florida distribution center

[20] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

lost its authority to distribute or dispense controlled substances, including opioids, for two years. This revocation ended in 2014.

70. The Jupiter Center supplied prescription opioids to two Walgreens pharmacies in Oviedo, Florida, one of which increased its oxycodone prescriptions from 6,600 dosage units in June 2010 to 169,780 dosage units in June 2011. Multiple arrests at the Oviedo Walgreens for illicit sales prompted the local chief of police to write letters to the Chairman and CEO of Walgreens and asked for their assistance in fighting the prescription drug epidemic. In the letter, the police chief reported that at both locations drugs were "sold, distributed as payment, crushed, and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."[21]

71. Defendant Walgreens' Jupiter Center continued to supply prescription opioids to the Oviedo pharmacies, and increased its quantities of 30 mg oxycodone from 73,300 tablets in February 2011, to 145,300 dosage units in July 2011. The Jupiter Center nearly doubled its distribution of oxycodone to one of these pharmacies within a six month period.

72. The Jupiter Center, along with Defendant Walgreens' headquarters, ignored warnings and concerns from its own employees about large shipments of opioids. In January 2011, the Center's Function Manager, who was responsible for all Schedule II drug operations (including opioids), sent an email to the manager of Walgreens' drug stores at its headquarters about the suspiciously "large quantity," of oxycodone that was being ordered by three stores in Florida.[22] The Jupiter Center continued to supply opioids to these locations, and provided a Walgreens' pharmacy in a town of less than 3,000 people, 285,800 30 milligram doses of oxycodone in January

[21] In the Matter of Walgreens Co. *Order to Show Cause*, September 13, 2012.

[22] *Id.*

2011. Despite the warning from an employee, Defendant Walgreens did not report any of these orders as suspicious.

73. Instead, Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," [23] underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

74. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

75. Walgreens' misconduct was not limited to Florida. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

76. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson

[23] *Id*.

admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[24] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[25] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers" including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from the Washington Court House, Ohio facility (among other facilities).[26]

[24] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[25] *Id.*

[26] Other facilities included McKesson's distribution centers in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; and West Sacramento, CA.

Washington Court House, Ohio is approximately an hour's drive from the Montgomery County seat of Dayton, Ohio, and upon information and belief, the McKesson facility located in Washington Courthouse Ohio supplied opioids to Montgomery County.

77. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[27] A DEA memo outlining the investigative findings in connection with the administrative case against the 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[28] The Washington Court House distribution center was among the warehouses investigators found "were supplying pharmacies that sold to criminal drug rings."[29]

78. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[30]

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[27] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[28] *Id.*

[29] *Id.*

[30] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

79. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

80. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally.

81. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted.[31] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[32] According to statements

[31] *Id.* (alteration in original).

[32] *Id.* (quoting a March 30, 2015 DEA memo).

of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[33] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[34]

82. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[35] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. Thats exactly what they did.[36]

83. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[37] He further explained that "I can tell you with 100

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[33] *Id.*

[34] *Id.*

[35] Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

[36] *Id.*

[37] *Id.*

percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[38]

84. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

85. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

86. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids

[38] *Id.*

consisted of a single page. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—9,500 pills *per day*.

87. The above violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders from which Defendants' operations in Ohio and the supply of opioids into Montgomery County would not have been exempt. In addition, these violations of federal law and regulations also constituted violations of Ohio law.

4. Defendants worked together to sustain their market and boost their profits.

88. As explained above, Defendants, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion, and which, in the case of Walgreens, were part of the same corporate family. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesaler distributors also offer marketing programs, patient services, and other software to assist their dispensing customers.

89. Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

90. Upon information and belief, each of the Defendants also worked together through trade or other organizations, such as the HDA, the National Association of Chain Drugstores ("NACDS"),[39] and the Pain Care Forum ("PCF"), to safeguard the market for opioids and the distribution of opioids.

91. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.

92. The closed meetings of the HDA's councils, committees, task forces and working groups provided Defendants with the opportunity to work closely with each other and with pharmaceutical companies, confidentially, to develop and further their common purpose and interests.

[39] The National Association of Chain Drug Stores is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Walgreens serves on the Board of Directors of NACDS.

93. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[40]

94. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences as "bring[ing] together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[41] These conferences provided HDA members "unmatched

[40] Councils and Committees, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/about/councils-and-committees

[41] 2017 Business and Leadership Conference, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/events/2017-business-and-leadership-conference.

opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry"[42] and an opportunity for Defendants to work together.

95. Defendants also worked together through joint efforts of the HDA and NACDS. The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

96. Defendants also coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—which has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[43] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, including through the enterprise described in this Complaint.

97. Taken together, the interaction and length of the relationships between and among the Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Defendants were not operating in isolation or groups forced to work together

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[42] *Id.*

[43] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

in a closed system. They operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

98. The HDA, NACDS, and the Pain Care Forum are examples of the overlapping relationships and concerted joint efforts to accomplish common goals, and demonstrate that the leaders of each of the Defendants were in communication and cooperation.

99. Publications and guidelines issued by the HDA confirm that Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an *amicus* brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.[44]

100. Defendants were also a part of a decision-making scheme seeking to control the state and federal government's response to the distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

101. Defendants worked to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. They did this through their participation in the PCF and HDA.

[44] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 5.

102. Defendants also worked to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

103. Defendants thus knew that their own conduct could be reported by other distributors and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

104. The desired consistency was achieved. As described below, Defendants failed to report suspicious orders and the flow of opioids continued unimpeded.

5. Defendants ignored red flags of abuse and diversion.

105. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database.[45] The data necessary to identify with specificity the transactions that were suspicious is in possession of the Defendants, but has not been disclosed to the public.

106. Yet, publicly available information confirms that Defendants funneled far more opioids into Montgomery County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Montgomery County.

107. The County's information and belief rests upon the following facts:

(a) wholesalers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes

[45] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) wholesalers regularly visit pharmacies to promote and provide their products and services, which allows them to observe red flags of diversion;

(c) Defendants together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

108. As discussed above, Montgomery County had an opioid prescription rate exceeding its population from 2006 to 2015, and that rate has remained high — an average of nearly 93 prescriptions per 100 people—thereafter.

109. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. For example, Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[46] The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

[46] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

110. According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports.

111. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Montgomery County, should have investigated, ceased filling orders for opioids, and reported potential diversion to law enforcement.

112. Publicly available data suggests distribution of opioids to Montgomery County exceeded reasonable medical use and that opioids were likely diverted into Montgomery County. As explained above, Montgomery County, with an average population from 2010 to 2017 of approximately 535,000, received a total of 310,583,228 retail doses of opioid analgesics, with a high of 42,280,396 in 2012. This amounted to 149 doses per opioid patient, 18 doses per person, and with an average of 12% of the population receiving an opioid over this time period. These figures suggest that within Montgomery County, there was a greater distribution of opioids than could be justified by legitimate medical need.

113. The volume of opioids distributed in Montgomery County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses. This is particularly true given that Montgomery County's supply of opioids even exceeded statewide figures—an already high baseline given Ohio's unfortunate placement at the epicenter of the opioid crisis.

114. Further, a prescriber in Montgomery County was recently convicted of crimes involving drug diversion. The indictment alleged the doctor was essentially operating a pill mill, taking cash payments in exchange for, at most, a cursory examination and prescription of excessive quantities of opioids, and rarely, if ever, receiving counseling on alternative treatment methods. Upon information and belief, this prescriber, and the pharmacies at which the providers' patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in Montgomery County, but specific instances of diversion. Notably, the same pharmacies, or pharmacy chains, appear multiple times in the recent indictment described above as having dispensed prescriptions to patients who later died of drug overdoses. In Ohio, physicians or clinics engaged in illicit prescribing have been found to frequently team with particular pharmacies to distribute prescription opioids.[47]

115. Another local prescriber, described as writing more opioid prescriptions than any other general practice physician in Ohio, permanently surrendered his license following an investigation by the State Medical Board of Ohio.

116. In addition, the crisis of fatal overdoses from prescription opioids in Ohio communities has been widely publicized for years. Montgomery County, is unfortunately, among the communities hardest hit by the opioid epidemic. The County has seen a dramatic rise in fatal drug overdoses. Many of these deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. The CDC estimates that for every opioid-related death, there are 733 non-medical users.

[47] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 6 (S.D. Ohio June 30, 2011).

Defendants thus had every reason to believe that illegal diversion was occurring in Montgomery County.

117. Not only were prescription opioids diverted within Montgomery County, upon information and belief, they were being diverted into Montgomery County from pill mills further south in Ohio, that, upon information and belief, these Defendants also failed to report or cease supplying. An epidemiological report from the Ohio Governor's Cabinet opiate action team cited the shutdown of southern Ohio pill mills as one of the chief factors in an increase throughout Ohio in heroin overdose rates (which, as explained below, is the drug turned to by prescription opioid users when those drugs are no longer available or too expensive). Consistent with the observed statewide trend, Montgomery County has seen a spike in heroin overdoses and lives lost to synthetic opiates, such as fentanyl.

118. In addition, upon information and belief, the Defendants would have known that Ohio's crack-down on pill mills within the state did not prevent suspicious orders from being placed in the state and ultimately diverted to illicit use in Ohio communities. For example, opioid manufacturer Mallinckrodt found in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida. During that time, Florida lacked a prescription drug monitoring program similar to Ohio, and traffickers would recruit others to travel to Florida to pick up the drugs Mallinckrodt, through wholesale distributors, had shipped there, and bring them back to Ohio, a route that became known as the "Florida Pipeline" or "OxyContin Express."[48] According to the *Washington Post*, an internal summary of a federal case against

[48] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

Mallinckrodt, described above, showed that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[49]

119. Upon information and belief, Defendants would have been aware that as Ohio cracked down on opioid suppliers, out-of-state dispensaries filled the gaps, directly impacting Montgomery County. As described above, Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

120. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price. In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone pipeline between Ohio and Florida."[50] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—

[49] The Government's Struggle to Hold Opioid Manufacturers Accountable: Sixty-six percent of all oxycodone sold in Florida came from this company. But the DEA's case against it faltered, *Washington Post*, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.256b39de1578

[50] *16 charged in 'pill mill' pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html.

paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. district judge Michael Watson, contributing to a "pipeline of death."[51]

121. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 for operating a pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states, including Ohio. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio.

122. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the PCB's customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio[.]"[52]

123. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg oxycodone pills manufactured by Mallinckrodt. Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, which runs directly through Montgomery County, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the

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[51] *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html.

[52] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

telltale out-of-state tag. If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.

124. Given Montgomery County's central location along the "Oxy Express" and at the intersection of major transportation thoroughfares, Defendants would have known that opioids were being diverted into the community. The County not only straddles two major trade corridors, it is near the country's median center of population, with more than half of the U.S. population living within 600 miles of Dayton. The County sits at the crossroads of Interstate 75, discussed above, and Interstate 70, described as the nation's "heroin highways," making illicit opioids both more accessible and less expensive.

125. The County forms part of the Ohio High Intensity Drug Trafficking Area ("HIDTA") designated by the U.S. Department of Justice National Drug Intelligence Center ("NDIC"). This designating requires, among other things, that an area be a "significant center of illegal drug production, manufacturing, importation, or distribution," that "State, local, and tribal law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem," and that "Drug-related activities in the area are having a significant harmful impact in the area and in other areas of the country."

126. In 2011, the NIDC described the overall drug threat in the Ohio HIDTA as increased, "particularly from increased trafficking and abuse of heroin and prescription opioids." The report specifically recognized that, "prescription opioid diversion and abuse are increasing, resulting in a significant overall threat from prescription and illicit opioid abuse within the HIDTA

region." Moreover, the "already high" availability of diverted prescription opioids was increasing. Dayton, in particular, was recognized as a frequent transshipment point.

127. By 2015, with the reduction of pill mills in Southern Ohio and low cost of heroin, heroin had become the major drug of concern in the Ohio HIDTA region. At the same time, "[p]rescription opioid diversion and abuse remain[ed] high and seizures continue[d] to grow."[53]

128. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Montgomery County.

B. DEFENDANTS HID THEIR LACK OF COOPERATION WITH LAW ENFORCEMENT AND FALSELY CLAIMED TO BE ACTIVELY WORKING TO PREVENT DIVERSION.

129. When a wholesaler does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

130. After being caught failing to comply with particular obligations at particular facilities, Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017,

[53] Executive Office of the President, Office of National Drug Control Policy, High Intensity Drug Trafficking Areas Program 2015 Report to Congress, at 104.

McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

131. More generally, the Defendants publically portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

132. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

133. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients." Another AmerisourceBergen representative has claimed publically, on behalf of the company that, "[a]s a supply chain partner, we are committed to finding comprehensive solutions to mitigate the opioid epidemic impacting our communities, and we understand the important role we play in helping to combat medication diversion and abuse[.]"

134. Walgreens, too, publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription, in accordance with state pharmacy regulations. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

135. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA (now HDA) and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[54]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

[54] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

136. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

137. These public statements created the false and misleading impression that the Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

C. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED THE COUNTY AND ITS RESIDENTS.

138. Defendants compounded the harms from aggressive marketing that overcame barriers to widespread prescribing of opioids for chronic pain by supplying opioids beyond even what this expanded market could bear, and by turning a blind eye to red flags that they were fueling abuse and diversion of these dangerous drugs.

139. By continuing to supply and failing to report suspicious orders of opioids, Defendants have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse.

140. Further, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication

as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids. The Director of Montgomery County's Alcohol, Drug Addiction, and Mental Health Services ("ADAMHS") Board estimates that, consistent with national statistics, as many as seventy-five percent of the people turning to heroin in the County began with prescription opioids and transitioned to illicit drugs when their prescription was cut off or they could otherwise no longer obtain these drugs. Similarly, Ohio's Prescription Drug Abuse Task Force has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high. Surveys have found the same response, with a participant explaining, for example, that "People start by using pain pills and then once they can't get those, they eventually go to heroin."[55]

141. Ohio's Prescription Drug Abuse Task Force similarly has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high. Likewise, a study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, finding that "[y]oung new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin," that several reported resorting to heroin after OxyContin became too expensive or difficult to obtain, and that "[a]buse of OxyContin prior to the abuse of heroin appears to be a common pattern."[56]

142. A relatively recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital

[55] Ohio Substance Abuse Monitoring Network, Drug Abuse Trends in the Dayton Region, January – June 2016.

[56] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

settings that, in synthetic form, has made its way into Ohio communities, including Montgomery County.

143. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. Because of its potency, the Ohio Attorney General's website recommends that chemists and lab technicians who test for carfentanil use protective gear.

144. Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."[57] In Ohio, an average of 14 people now die, per day, from fatal drug overdoses. Provisional data from the CDC showed the crisis continuing to explode during the first half of last year, with 5,232 Ohio overdose deaths recorded in the 12 months ending June 31, 2017. Further, even these grim numbers likely understate the number of lives lost due to incomplete reporting.

145. Even in the midst of such staggering statewide statistics, Montgomery County stands out. In June 2017, the County was reported to have more overdose deaths per capita than anywhere else in the nation. Measured over the five-year period from 2009 to 2014, Montgomery County had the second highest death rate from drug overdoses in the state of Ohio. Since 2010, the County saw a 104% increase in the number of people who died from unintentional drug overdoses. In 2017, the County recorded its highest number of overdose deaths – 559 lives lost. "Similar to previous years, about 90% (specifically, in 2016, 93%) of the deaths involved at least

[57] *Id.*

one opioid, including prescription opioids, heroin, and/or illicit fentanyls."[58] Each year since, 2010, the number of people who died in Montgomery County from fatal drug overdoses has continued to rise.

146. The coroner has described the local morgue as "full every night." At times, it is more than full, a reality difficult to describe without minimizing the heartbreak of each lost life. This new reality marks so great a departure from the County's history and expectations that the coroner's office has had to hire additional staff and renovate its coolers to provide additional space. In addition, the coroner's office has been obliged at times to rent rooms in local funeral homes. The County has also had to rent refrigerated trucks, which it parked behind the morgue, to keep the overload of bodies.

147. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose. The number of people receiving treatment from hospital inpatient and emergency department (ED) visits for heroin overdoses soared from 2012 to 2015, with hospitals treating most of these patients in ED settings. In 2015 alone, Montgomery County Emergency rooms treated 293 people for heroin overdoses —more than 6 times as many people as in 2012. The number of patients requiring inpatient treatment for heroin overdoses also sharply increased, from eight people in 2012 to 27 just three years later. Opioid addicts are so familiar with the potential for overdose that many choose to use drugs in public places, such as a Walmart bathroom, where they can be found and revived.

[58] Public Health – Dayton & Montgomery County & the Montgomery County Coroner's Office, Final Report, Montgomery County Poisoning Death Review 2010-2016 at5 (June 1, 2017).

148. According to data collected in the first six months of 2017, Montgomery County ranked second in Ohio for the highest rate of drug overdose visits to emergency rooms, and five of the top ten counties were located in West Central Ohio. From January 1, 2017 to June 30, 2017, Montgomery County residents made 2,565 emergency room visits for drug overdoses — an average of 14.2 visits per day.

149. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37% of admissions for drug abuse were associated with a primary diagnosis of opioid abuse or dependence. According to a 2015 poll, 3 in 10 Ohio adults have family members or friends who have experienced problems as a result of abusing prescription pain relievers, a steep rise from only a year earlier, and 2 in 10 Ohio adults had family or friends whom they described as experiencing problems from using heroin. Of these Ohioans, 4 in 10 knew someone who had overdosed due to a pain drug, and 6 in 10 knew someone who had overdosed on heroin.

150. Opioids have caused injury and illness in Montgomery County in other respects as well. An increase in Hepatitis C, according to the CDC, is directly tied to intravenous injection of opioids. The number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011-2015, an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers, stemming from the opioid epidemic. The co-morbidity is sufficiently high that the Ohio Department of Health recommends that women of childbearing age who have tested positive for drug and dependence also receive screening for Hepatitis C and HIV. People injecting heroin also have developed infections requiring IV antibiotics administered at an extended to care facility.

151. The oversupply of opioids also has had a significant detrimental impact on children in Montgomery County. Young children have access to opioids, nearly all of which were prescribed or supplied to adults in their household. If parents become addicted and turn to illicit

opiates, children risk overdose from these drugs as well. Dayton's Children's Hospital has been treating as many as two children per week for accidental exposure to drugs suspected to be opiates. Toddlers are particularly at risk, as they routinely put things in their mouths as they crawl and explore their world. In May of 2017, a thirteen-month-old girl, was discovered not breathing in her grandmother's home. EMS responded, but she could not be revived; an autopsy later showed fentanyl and carfentanil as the cause of death. Shortly thereafter, emergency responders answered a call on behalf of a two-year old girl unconscious from a suspected opioid overdose. A two-year old boy was pronounced dead after being taken to Good Samaritan hospital in 2016. More recently, a ten-month old baby had to be revived with Narcan after coming into contact with fentanyl.

152. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

153. In Ohio, the number of infants born with NAS increased six-fold in from 2004 to 2011. From 2009 to 2014, data from seven regional hospitals showed a greater-than six-fold

increased in drug-exposed infants. As a whole, the State has seen an 816% increase in the number of infants born with NAS from 2006 to 2015, with opioids and other illegal narcotics being the most commonly implicated drugs since 2009. In 2015 alone, 2,174 infants were admitted to inpatient settings for this painful condition, an average of six per day. NAS has become so prevalent in Ohio communities that the state's Department of Health now recommends screening all newborns for this condition.

154. This dramatic rise in NAS may be described as an epidemic within an epidemic. According to the Ohio Perinatal Quality Collaborative, the "NAS epidemic is steadily increasing, overwhelming social service systems and public payers." In 2013, the average inpatient stay and bill for babies suffering from NAS was four times longer and four times higher than for other infants in Ohio. Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million. Ohio's healthcare system alone has contributed more than $133 million to NAS-related hospital charges in 2015. If these infants are placed in foster care, the County pays for the NAS services. With the opioid epidemic, treating infants for NAS has become a new normal for Dayton Children's Hospital. The hospital's neonatal intensive care unit treats 20 to 30 babies a year for NAS, with an average stay of 17 days. Meanwhile, at least two babies have been born inside the jail instead of the hospital.

155. In addition, volunteers have been recruited and trained to cuddle babies as they withdrawal. And, a local non-profit recently opened to provide a place to care for some of these infants and work with families to provide a safety net. A number of County agencies, including Children Services, the Family Treatment Court, the men's drug court, and the women's drug court have worked collaboratively to help parents obtain treatment, find voluntary placements for children with relatives, and provide mothers time to heal and demonstrate they can safely parent.

Children Services works in tandem with the non-profit to ensure safety. The —heriff's office, recognizing that jails are not best equipped to be treatment centers, also has collaborated to get people into treatment.

156. Further, "[c]hildren of parents addicted to opiates," have been described as the "invisible victims of the epidemic," are "flooding into the state's child protection system."[59] Statewide, the opioid epidemic is largely responsible for the 9% increase in the numbers of children - nearly 1,100 – placed in the care of Ohio child protection agencies between 2011 and 2015. Seventy percent of infants placed in Ohio's foster care system are children of parents with opioid addictions. These figures, too understate the impacts on children, as they do not account for children who are placed in kinship care or who receive public services without being displaced from their homes.

157. That is particularly true in Montgomery County, which for years has made placing children with relatives a high priority. Further, families in the County often make alternative arrangements that do not result in formal entry into the foster care or child services system, but in which a parent is no longer the primary caregiver. In Ohio, there has been a 62% increase in the number of children placed in a relative's care between 2010 and 2016. As of May 2017, approximately 124,000 children – 5% of the children in the state, were being raised by relatives other than their parents.

158. In the County, as many as 40% percent of the children entering foster care are removed from homes in which substance abuse is a factor. That estimate has increased as additional information is gathered, and is likely even higher. In 2016, 322 children in the County entered foster

[59] Public Children Services Association of Ohio (PCSAO), http://www.pcsao.org/programs/opiate-epidemic

care for reasons that included heroin or prescription opioid use, and in 2017, that number rose to 367 removed from homes with these drugs. In some cases, multi-generational drug use may make placement with relatives difficult. For example, one child placed with his grandmother had to be uprooted again when his grandmother overdosed and died. Many of these children are infants who are suffering from NAS and facing physical, as well as emotional, harm. As the former Assistant Director of Children Services, and now Director, has explained: "The impact on the system has been devastating. Children-services agencies throughout the state are struggling to find homes for these kids who are often babies, who just really need a loving family environment, either temporarily while the parent recovers from addiction, or permanently when the parent has died from an overdose or simply cannot beat the addiction."[60] As many as 65 percent of children removed from their home by Children Services are never able to return to their families.

159. Children removed from homes with drug abuse tend to stay in foster care longer and to enter foster care having experienced more significant trauma, which makes their care more expensive. Many of these kids watched their parents overdose or die," according to the executive director of the Public Children Services Association of Ohio ("PCSAO"), a statewide membership organization for county children services agencies.[61] Children may have gone days without food or supervision, and older children may have functioned as surrogate parents to their younger siblings, reported Ohio's Attorney General.[62] A statewide report found that increasingly, children

[60] Herry Kenney, Feds Award Family Drug Court Treatment Program $21 Million to Expand (Oct. 19, 2017), http://wyso.org/post/feds-award-family-drug-court-treatment-program-21-million-expand

[61] Chris Stewart, *Foster Care Report: 'Many of these kids watched their parents overdose or die,'* Dayton Daily News, available at https://www.mydaytondailynews.com/news/foster-care-report-many-these-kids-watched-their-parents-overdose-die/X4ytHHs6IlO5D8GseUQclK/; http://www.pcsao.org/programs/opiate-epidemic

[62] *Id.*

entering the foster care system from homes with drug abuse are dealing with significant mental health issues, requiring intensive treatment that may cost as much as $200 to $400 a day, because of what they have seen or experienced. Ohio has the heaviest reliance on local dollars for child protection services of any state in the nation, with counties shouldering more than half of the costs through local government funds and dedicated levies.

160. The Dayton Daily News has reported that a local couple certified as foster parents ten years ago recalled that, while they were told to expect to wait two or three years for a baby, with their foster license, a baby now could be placed with them within a week. Montgomery County is one of eight Ohio counties chosen for a new pilot program by the state to aid children placed in foster care due to substance abuse, and will have a full-time staff member responsible for family searches and engagement. The County's Children Services agency has received as many as 10,000 child welfare calls a day, and for the year 2017 had an average of 655 children in its custody. Meanwhile, it has provided in-home services for hundreds of children as well. Children Services also recently implemented a "30 Days to Family" program, which uses technology and other resources to aid in family search and engagement, with the aim of having each child placed in foster care placed with a stable family member within 30 days.

161. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily. A recent report by The Ohio State

University estimated that in Ohio, in 2015 alone, "opioid overdoses resulted in $3.8 billion in lost lifetime productivity" and "[i]n total, the cost of opioid abuse and dependency ranged from $6.6 billion to $8.8 billion."[63]

162. The County also has faced increased costs associated with increased drug crimes, including costs for prosecutors, jail costs, costs of adult probation, indigent defense, common pleas court operations, drug court operations, juvenile court operations, and juvenile probation and detention. From 2013-2015, there was an average of 5,150 jail bookings per year for drug related offenses. In 2016 alone, law enforcement agencies in the County recorded a combined total of 149 prescription drug offenses and 694 heroin offenses. A report by the Montgomery County Drug Free Coalition estimated that as many as half of the daily jail population is booked with drug charges or have had prior bookings involving drugs. More recently, in 2018, the Sheriff's office continued to observe that the vast majority of inmates were incarcerated for opioid-related crimes.

163. Deputies frequently arrest people who are so intoxicated that they must take them to jail by way of the local hospital. Out of concern that people will conceal and then consume drugs they carry when arrested, the jail has drastically changed its intake area "completely because of the opioid issue," according to the jail administrator and court security officer for the sheriff's office.[64] At significant expense, the jail took a cell out of service to create a room large enough to house a newly acquired body scanner needed to help corrections officers find contraband. The need to detect concealed drugs exists in part, because people addicted to opioids may so fear the

[63] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 8.

[64] Charlotte Cuthbertson, *America's Jails Swamped by Opioid Crisis*, (Jan. 30, 2018), https://www.theepochtimes.com/americas-jails-swamped-by-opioid-crisis_2421013.html

detox process that they risk additional felony counts by bringing drugs into the jail. Even with these efforts, since January of 2016, there have been 87 doses of Narcan administered at the jail.

164. The opioid epidemic in the County is so severe that, in June of last year, the jail hired a treatment coordinator, primarily in response to the opioid crisis. Intended to serve as an "air traffic controller" for health services contracts at the jail, and devotes the majority of her time finding drug treatment for inmates, including medication assisted treatment. The jail also reconfigured another area to house women, who increasingly filled the jail as the opioid crisis began, and who now make up twenty percent of its population, a number that would be even higher if it were not for the specialized Women's Therapeutic Court, a specialized docket for drug offenders run by the County. Many of these women are mothers still carrying their babies, and the jail assumes the cost of care during the pregnancy, including the cost of specialized medical care, secure transportation to doctor visits, and, in some cases, the child's birth in a hospital.

165. The Common Pleas Court's Secure Transitional Offender Program ("STOP" Program) which provides court-sanctioned or court-ordered residential drug treatment, doubled its previous capacity and began serving women as well as men in 2016. It is now a 96-bed facility that that maintains capacity at all times, without maintaining any waiting list. The program which boasts a successful graduation rate of 95%, aims to directly address each person's specific needs, expedite access to treatment services, maximize the effective use of jail beds, require probationers to pay back the community through work detail and community service projects, and provide a continuity of care through community risk reduction services. This does not include the increased costs from non-drug offenses, such as burglary, robbery, elder abuse, prostitution, or domestic violence, that also are related to opioid use. The program, which reflects one effort to push back against the opioid epidemic in the County, has offered hope to participants, especially younger

people who participate. The County put approximately $80,000 into updating and renovating a facility to house the program. And, although less expensive than jail, the STOP Program represents a significant financial commitment, costing approximately $53-$63 per day for each person participating.

166. Public Health - Dayton & Montgomery County's Addiction Services provides substance use disorder treatment, services, including screening and assessment, outpatient counseling, intensive outpatient counseling, family counseling, a home-based counseling team, referral to other treatment and Mental Health Services. Through outreach services, Public Health, also goes into the community to reach those in need of substance use disorder and related services, works with community businesses and faith-based communities, and works through the courts and the police departments to assist in addiction related problems.

167. In 2013, the County established the Montgomery County Drug-Free Coalition, which brings together diverse partnerships to enhance and expand efforts to combat drug abuse, and works with health, education, faith-based, and non-government organizations to help combat the epidemic.

168. The County also seeks to reach people in need of help through a new, 24/7 CrisisCare program expansion which offers secure transport from a hospital and immediate entry to treatment to those rescued from opioid overdoses by Narcan. Free classes and naloxone kits are provided weekly at a local non-profit through Montgomery County Project DAWN. Health officials have attributed the slow-down in overdose deaths in the second half of 2017 in part to the availability of naloxone.

169. In the fall of 2016, the County started the Community Overdose Action Team, addressing aspects of addiction, including prevention, treatment, and recovery, through an inter-

agency model with eight different divisions or focus areas ranging from increasing access to addiction treatment to curbing the illegal drug market. By working collaboratively across county agencies and with the community, the Community Overdose Action Team, which has grown to include more than 200 people from more than 100 organizations, has built positive momentum towards solving the ongoing opioid crisis in the County.

170. As part of its efforts, the County has increased funding for residential treatment facilities. Specifically, the County has doubled the number of residential withdrawal management beds it makes available through Nova Behavioral Health to twelve, and estimates the changes will make withdrawal management available to over 1,000 people annually, and implemented a new program to provide recovery housing for between 16 to 32 pregnant women annually. In addition, the County has nearly completed renovating and repurposing the Dora Lee Tate Center to provide a juvenile residential treatment center, thereby addressing a significant need. The County will spend $6.5 million for this center alone.

171. Public Health also recently opened a new medication assisted treatment facility in the fall of 2017. The agency has added other new and expanded services as well. On August 1, 2017, the Department of Public Health, through Samaritan Behavioral Health, Inc., launched a new Ambulatory Withdrawal Management Services program. This 10-day outpatient detoxification program serves up to 20 people per week (1,040 annually), through medication-assisted treatment, a symptom management and abstinence planning group, case management, and referrals for on-going treatment.

172. Additionally, the County expanded access to ADAMHS services for inmates in the Montgomery County Jail already involved with addiction and mental health treatment through an

ADAMHS agency. All inmates are assessed upon intake into the jail so that ADAMHS can continue to provide treatment for addiction and mental health issues while they are jailed.

173. The County has provided $3.5 million for these new and expanded services alone.

174. More broadly, the ADAMHS Board alone spent more than $17.4 million to address the opioid epidemic in 2016 and more than $20.4 million in 2017, including expenses related to preventative information, education, and programing, Naloxone and other crisis intervention services, criminal justice services, ambulatory withdrawal management, recovery housing, residential withdrawal management, and other addiction treatment services.

175. In addition to these expanded services, the County initiated CarePoint, a syringe exchange program operated by Public Health, Dayton & Montgomery, on April 17, 2015. The program has since expanded, and currently distributes at three separate centers. At each visit, Carepoint offers clients referrals for drug treatment, medical care and dental care, mental health care, on-site medical testing for pregnancy, HIV, Hepatitis C, and Syphilis, Medicaid enrollment assistance, and social services such as clothing, food, and housing assistance. The program also distributed 823 Narcan kits and 612 Narcan refills for kits already used to address overdoses. At least 451 of the kits used reported to have revived the overdose victim. The program identified 513 new clients in 2017, more than 52% of whom had a prior overdose. Of those new clients who had survived an overdose, more than 65% had overdosed more than once. In 2017, Carepoint reported 4,945 client encounters, over 2,000 more than in 2016 (an increase of more than 71%).

176. After seeing a 132 percent increase in child welfare cases where opiates were noted as a reason for action between 2009 and 2013, the County developed the Montgomery County Family Treatment Court, which began seeing clients in October of 2016. The Family Treatment Court, a collaborative effort between the Montgomery County Juvenile Court, Montgomery

County Family Services, and Case Western Reserve University, aims to ensure a healthy, nurturing, and drug-free home for children, reunify families, and avoid options such as foster care where possible. The program offers out-patient care for parents struggling with addiction, judicial monitoring, and individualized family support services. Reunification rates are some 20-40 percent higher for Family Treatment Courts than a comparison group, and children of Family Treatment Court participants spend less time in foster care and out-of-home placements. Already, the County's treatment court has successfully graduated its first class of participants, and has seen children reunited with their parents or able to remain at home under supervision. The court's resources more than doubled after it was selected as one of three nationwide recipients of a federal Family Drug Court implementation grant, evidencing confidence in the program. While this is a significant step forward, according to the presiding judge, there remains a larger, unmet need in the community.

D. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FORM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct.

177. The County contends it continues to suffer harm from the unlawful actions by the Defendants.

178. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

179. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceived Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State and the County that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State and the County, that they are working to curb the opioid epidemic.

180. Defendants deliberately and successfully concealed from the medical community, patients, and the County facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

181. Defendants also fraudulently concealed their misconduct. They have declined to release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion and publically portray themselves as committed to fighting the opioid epidemic. However, their public pronouncements are at odds with their concealed misconduct.

182. To the extent that information about Defendants' violations of the federal CSA and its implementing regulations was disclosed through settlement agreements, that information, until McKesson's 2017 settlement, concerned facilities outside Ohio. Further, such settlement agreements have typically been followed by or coupled with promises to improve compliance.

E. FACTS PERTAINING TO CLAIMS UNDER THE OHIO CORRUPT PRACTICES ACT ("OCPA")

183. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[65] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, Defendants AmerisourceBergen, Cardinal, and McKesson (the "Supply Chain Defendants") worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

184. As explained above, regulations adopted under the CSA, as well as Ohio statutes and regulations, require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

185. As "registrants" under the CSA, the Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[66] Ohio law is no less stringent.

186. If morality and the law did not suffice, competition dictates that the Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a distributor could gain market share by reporting a competitor's illegal behavior (causing it to

[65] http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response
[66] 21 C.F.R. 1301.74(b).

lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA and Ohio law, this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the CSA, Ohio law, including the Ohio Corrupt Practices Act ("OCPA").

187. The Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the Supply Chain Defendants apparently all found the same

profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

188. As described above, at all relevant times, the Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

189. At all relevant times, as described above, the Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

190. The Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

c. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

d. they did not have the capability to identify suspicious orders of controlled substances or were in the midst of a learning curve.

191. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[67]

192. The CSA and the Code of Federal Regulations, require the Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

193. The Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA. Specifically, the Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports.

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[67] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

194. The Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

195. In devising and executing the illegal scheme, the Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

196. For the purpose of executing the illegal scheme, the Supply Chain Defendants committed incidents of corrupt activity, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These incidents of corrupt activity, which included repeated acts of mail fraud, wire fraud, and telecommunications fraud, constituted a pattern of corrupt activity.

197. The Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Distributor Defendants or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated requests for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the purchase and sale of prescription opioids;

d. Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated Supply Chain Defendants' DEA registrations;

f. Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments to the Supply Chain Defendants' lobbyists through the PCF;

k. Payments to the Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

l. Deposits of proceeds from the Supply Chain Defendants' distribution of prescription opioids; and

m. Other documents and things, including electronic communications.

198. Each of the Supply Chain Defendants identified shipped, paid for and received payment for the drugs identified above, throughout the United States.

199. The Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

200. At the same time, the Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to

preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

201. The Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

202. The Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

203. The mail and wire transmissions described herein were made in furtherance of the Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

204. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, the County has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

205. The Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme.

206. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

207. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

208. As described above, the Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the Supply Chain Defendants supports this conclusion that the Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

209. Each instance of corrupt activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Montgomery County, and its residents. The Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on the County and its residents. The Supply Chain Defendants were aware that the County and its residents rely on these Defendants to maintain a closed system of distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

210. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of corrupt activity.

CAUSES OF ACTION

COUNT I
Statutory Public Nuisance
(Against All Defendants)
(*Brought by the County of Montgomery and the State of Ohio ex rel. Mathias H. Heck, Jr. Prosecuting Attorney, each as the Plaintiff in this Count*)

211. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

212. The Prosecuting Attorney for Montgomery County, Mathias H. Heck, Jr., brings this claim in the name of the State of Ohio pursuant to the statutory authority granted under R.C. § 3767.03, to abate a public nuisance and to enjoin further maintenance of the nuisance. R.C. § 3767.03 provides: "Whenever a nuisance exists the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation in which the nuisance exists; the prosecuting attorney of the county in which the nuisance exists; the law director of a township that has adopted a limited home rule government under Chapter 504. of the Revised Code; or any person who is a citizen of the county in which the nuisance exists may bring an action in equity in the name of the state, upon the relation of the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation; the prosecuting attorney; the township law director; or the person, to abate the nuisance and to perpetually enjoin the person maintaining the nuisance from further maintaining it."

213. The Prosecuting Attorney for Montgomery County also brings this claim in the name of the State of Ohio pursuant to the statutory authority granted under O.R.C. § 4729.35 to enjoin a violation of that statute.

214. Ohio statutory law provides that "[a]s used in all sections of the Revised Code relating to nuisances . . . (C) "Nuisance" means any of the following: . . . (1) [t]hat which is defined and declared by statutes to be a nuisance . . . ." R.C. § 3767.01.

215. Ohio statutory law "declare[s] to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance" "[t]he violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011 of the Revised Code . . . ." R.C. § 4729.35.

216. Opioids are "a drug of abuse" as defined in R.C. § 3719.011.

217. Under R.C. § 3767.02, "Any person, who uses, occupies, establishes, or conducts a nuisance, or aids or abets in the use, occupancy, establishment, or conduct of a nuisance; the owner, agent, or lessee of an interest in any such nuisance; any person who is employed in that nuisance by that owner, agent, or lessee; and any person who is in control of that nuisance is guilty of maintaining a nuisance and shall be enjoined as provided in sections 3767.03 to 3767.11 of the Revised Code."

218. Defendants are persons who have established or conducted a nuisance, who have aided or abetted in the establishment or conduct of a nuisance, and/or who are in control of a nuisance and guilty of maintaining a nuisance; as defined in R.C. § 3767.02.

219. Defendants are persons who have violated, and/or who have aided and abetted the violation of the laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in R.C. § 3719.011.

220. In the distribution and sale of opioids in Montgomery County, Defendants violated and/or aided and abetted the violation of Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and Ohio Admin. Code ("O.A.C.") §§ 4729-9-12, 4729-9-16, 4729-9-28, and federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 CFR § 1301.74.

221. Defendants' unlawful conduct includes violating and/or aiding and abetting the violation of federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to stop or suspend shipments of suspicious orders; and

d. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

222. In the distribution and sale of opioids in Ohio and Montgomery County, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

223. The exemption in R.C. § 2925.02 only applies to drug wholesalers and distributors when their "conduct is in accordance with Chapters RC 3719., 4715., 4723., 4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

224. Defendants' conduct entails a pervasive pattern and practice of violating the statutes and regulations set forth above. Defendants' systemic failure to adhere to Ohio and federal controlled substances statutes and regulations has created an ongoing, significant, unlawful, and unreasonable interference with the public health, welfare, safety, peace, comfort, and convenience in Montgomery County.

225. Defendants had control over their conduct in Montgomery County and that conduct has had an adverse effect on the public right. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

226. The nuisance created by Defendants' conduct is abatable.

227. Defendants' misconduct alleged in this case is ongoing and persistent.

228. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

229. The Plaintiff has incurred expenditures for special programs over and above its ordinary public services.

230. The unlawful conduct of each Defendant was a substantial factor in producing harm to the Plaintiff.

231. The Plaintiff seeks abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance.

232. The Plaintiff seeks all other equitable relief as allowed by law.

COUNT II
Common Law Absolute Public Nuisance
(Against All Defendants)
(Brought by the County of Montgomery Board of Commissioners, the Plaintiff in this Count)

233. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

234. Defendants created and maintained a public nuisance which proximately caused injury to the County.

235. A public nuisance is an unreasonable interference with a right common to the general public.

236. Defendants have created and maintained a public nuisance by distributing and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Montgomery County, and the County and its residents have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

237. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

238. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of distributing and selling opioids, which are dangerously addictive drugs, in a

manner which caused prescriptions and sales of opioids to skyrocket in Montgomery County, flooded Montgomery County with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to the County and its residents.

239. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Montgomery County and its residents.

240. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Montgomery County and its residents. *See* Restatement (Second) of Torts § 821B.

241. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

242. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers have lost the value of productive and healthy employees; and

f. Increased costs and expenses for the County relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

243. Defendants intentionally and unreasonably and/or unlawfully pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Montgomery County, a higher level of fear, discomfort and inconvenience to the residents of Montgomery County, and direct costs to the County.

244. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to the County.

245. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Montgomery County constitutes an absolute public nuisance. *See e.g.* R.C. § 4729.35 ("The violation by a . . . person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse . . . constitute[s] a public nuisance[.]").

246. In the sale and distribution of opioids in Ohio and Montgomery County, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and

Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-912, 4729-9-16, and 4729-9-28.

247. Defendants' unlawful nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

248. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

249. Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

250. In the distribution and sale of opioids in Ohio and Montgomery County, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

251. Defendants are in the business of selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

252. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of disregarding their obligations to maintain effective controls against diversion and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the County—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

253. Defendants had control over their conduct in Montgomery County and that conduct has had an adverse effect on rights common to the general public. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion,

including whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

254. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the County described herein.

255. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

256. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Montgomery County and the harm inflicted outweighs any offsetting benefit.

257. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

258. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, the County has taken proactive measures to abate the public nuisance, and the County seeks to expand these efforts.

259. The nuisance created by Defendants' conduct is abatable.

260. Defendants' misconduct alleged in this case is ongoing and persistent.

261. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

262. In order to abate the public nuisance, the County has incurred expenditures for special programs over and above its ordinary public services.

263. The County seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

264. The County has suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Ohio citizens at large. These are harms that can only be suffered by the County.

265. The County is asserting its own rights and interests and its claims are not based upon or derivative of the rights of others.

266. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

267. The tortious conduct of each Defendant was a substantial factor in producing harm to the County.

268. The County has suffered an indivisible injury as a result of the tortious conduct of Defendants.

269. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

270. The County asserts this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, the County does not seek damages for death, physical injury to person, emotional distress, or physical damage to property, as defined under the Ohio Product Liability Act.

271. The County seeks all equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, attorney fees and costs, and pre- and post-judgment interest.

COUNT III
Violation of The Ohio Corrupt Practices Act
Ohio Revised Code § 2923.31, *et seq*.
Against McKesson, Cardinal, and AmerisourceBergen
(The "Opioid Supply Chain Enterprise")
(*Brought by The County of Montgomery Board of Commissioners, the Plaintiff in this Count*)

272. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

273. The County brings this Claim against Defendants McKesson, Cardinal, and AmerisourceBergen (the "Supply Chain Defendants"), each of whom is a "person" within the meaning of Ohio Rev. Code Ann. § 2923.31(G).

A. <u>The Opioid Supply Chain Enterprise and Pattern of Corrupt Activity</u>

274. The Defendants are "persons" within the meaning of R.C. § 2923.31(G) who conducted the affairs of an enterprise through a pattern of corrupt activity, in violation of R.C. § 2923.31.

275. The County is a "person," as that term is defined in R.C. § 2923.31, who was injured in its business or property as a result of Defendants' wrongful conduct.

276. Under R.C. § 2923.32:

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
>
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.

> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

277. Defendants conducted the affairs of an enterprise through a pattern of corrupt activity, hereinafter the "Opioid Supply Chain Enterprise," in violation of R.C. § 2923.32.

278. Defendants together were members of a legal entity enterprise within the meaning of R.C. § 2923.31(C). These Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the "Opioid Supply Chain Enterprise." The Opioid Supply Chain Enterprise consists of these Defendants, including their employees and agents. Along with the Defendants, trade organizations, including the HDA and PCF participated in the enterprise.

279. Alternatively, each of the above-named Defendants constitutes a single legal entity or associated-in-fact "enterprise" within the meaning of R.C. § 2923.31(C), through which the members of the enterprise conducted a pattern of corrupt activity. The Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the Supply Chain Defendants.

280. The Supply Chain Defendants were members the Healthcare Distribution Alliance (the "HDA"). Each of the Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of corrupt activity that gives rise to the Count.

281. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the Supply Chain Defendants; (b) was separate and distinct from the pattern of corrupt activity in which the Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Supply Chain Defendants; (d) was characterized by interpersonal relationships among the Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each of the Supply Chain Defendants conducted and participated in the conduct of the affairs of this Enterprise through a pattern of "corrupt activities" as defined in Ohio Rev. Code Ann.§ 2923.31(I)(1) and (2).

282. Corrupt activities as defined in R.C. § 2923.31(I) include, among other things: engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in any conduct defined as racketeering activity under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. § 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended; and, any "violation of [R.C.] section . . 2913.05."

283. A "'pattern of corrupt activity' means two or more incidents of corrupt activity, whether or not there has been a prior conviction, that are related to the affairs of the same enterprise, are not isolated, and are not so closely related to each other and connected in time and place that they constitute a single event." R.C. § 2923.31(E).

284. The Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of corrupt activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343 and R.C. 2913.05) within the past ten years. The multiple acts of corrupt activity that the Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, and posed a threat of continued racketeering activity. The corrupt

activity was made possible by the Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in intrastate and/or interstate or foreign commerce.

285. The Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States. The Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

286. Each of the Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

287. The Supply Chain Defendants' incidents of corrupt activity include, but are not limited to:

> Mail Fraud. The members of the Opioid Supply Chain Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling opioids for chronic pain.

Wire Fraud: The members of the Opioid Supply Chain Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling opioids for chronic pain.

Telecommunications Fraud: The members of the Opioid Supply Chain Enterprise violated R.C. § 2913.05 by "knowingly disseminat[ing], transmit[ing], or caus[ing] to be disseminated or transmitted by means of a wire, radio, satellite, telecommunication, telecommunications device, or telecommunications service any writing, data, sign, signal, picture, sound, or image with purpose to execute or otherwise further the scheme to defraud."

Violation of Controlled Substances Act. The members of the Opioid Supply Chain Enterprise violated 21 U.S.C. § 483(a)(4), which makes it unlawful "for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information form, any application, report, record or other document required to be made, kept or filed under this subchapter," and a violation of which is punishable by up to four years in jail, *see* 21 U.S.C. § 483(d)(1), making it a felony.

288. The Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

289. The Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in distributing prescription opioids.

290. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding distribution of prescription opioids and refusing to report suspicious orders.

291. As described herein, the Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same

or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

292. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

293. The pattern of corrupt activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the Supply Chain Defendants are distinct from the enterprise.

294. The pattern of corrupt activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

295. Many of the precise dates of the Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

296. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of corrupt activity.

297. It was foreseeable to the Supply Chain Defendants that the County would be harmed when they refused to report and halt suspicious orders, because their violation of their duties imposed by statute and regulation allowed the widespread diversion of prescription opioids

out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

298. The last incident of corrupt activity occurred within five years of the commission of a prior incident of corrupt activity.

299. For over a decade, the Supply Chain Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Supply Chain Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. As "registrants" under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"), the Supply Chain Defendants operated and continue to operate within a "closed-system." The CSA and Ohio law restrict the Supply Chain Defendants' ability to distribute Schedule II substances like opioids by: (1) requiring them to make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids; (2) register to distribute opioids; (3) maintain effective controls against diversion of the controlled substances that they distribute; and (4) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

300. As alleged above, Congress created a closed-system when it enacted the CSA, including the establishment of quota system, with the specific intent to protect public safety by reducing or eliminating the diversion of Schedule II drugs, like opioids, from legitimate channels of trade to illicit markets "by controlling the basic ingredients needed for the manufacture of [controlled substances.]"[68] Each of the Supply Chain Defendants knows and has known for

[68] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)

decades that if they do not report, investigate or halt suspicious orders, the likelihood of the DEA learning of these illicit transactions and diversions in a timely manner, or at all, is greatly reduced and, therefore, is likely to contribute to the increase and maintenance of artificially high quotas.

301. As described above, the County's allegations in this Count are based on violations of each of the legal duties, statutes, and regulations described in this Complaint, including the violations of Ohio laws and regulations.

302. Each of the Supply Chain Defendants also knows, and has known for decades, that the quotas for their opioid products will decrease or increase as the number of licit prescriptions decrease or increase.

303. Therefore, finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Supply Chain Enterprise engaged in the common purpose of fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids. The Supply Chain Defendants formed and pursued their common purpose through the many personal interactions that they had, confidentially, in organizations like the Pain Care Forum and the Healthcare Distribution Alliance.

304. The Supply Chain Defendants' common purpose and fraudulent scheme to unlawfully increase the DEA quotas violated the Corrupt Practices Act in three ways. First, the Supply Chain Defendants violated the Corrupt Practices Act because they engaged in the felonious distribution, selling, or otherwise dealing in controlled substances that are punishable by law in the United States. Specifically, the Supply Chain Defendants engaged in the distribution of controlled substances in violation of 21 U.S.C. § 843 because they furnished false or fraudulent material information in, and omitted material information from, applications, reports, records, and

other document they were required to make, keep, or file under required to be made, kept, or filed under this subchapter or subchapter II of 21 U.S.C. 801, *et seq*.

305. Second, the Supply Chain Defendants violated the Corrupt Practices Act by engaging in mail and wire fraud. The Supply Chain Defendants' common purpose and fraudulent scheme was intended to, and did, utilize interstate mail and wire facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

306. Third, the Supply Chain Defendants violated the Corrupt Practices Act by engaging in telecommunications fraud. The Supply Chain Defendants' common purpose and fraudulent scheme was intended to, and did disseminate or transmit writings, data, signs, signals, pictures, sounds or images by means of wire, radio, satellite, telecommunication, telecommunications devices or services in furtherance of the scheme to defraud.

307. The Supply Chain Defendants' fraudulent scheme arises at the intersection between the quotas governing the Supply Chain Defendants' prescription opioids and the Supply Chain Defendants' duty to identify, report, and halt suspicious orders of controlled substances. The Supply Chain Defendants' formed an enterprise with the intent to fraudulently increase the quotas for prescription opioids by refusing to identify, report and halt suspicious orders, thereby omitting both the fact and the Supply Chain Defendants' knowledge of widespread diversion of prescription opioids into illegitimate channels. The Supply Chain Defendants engaged in systematic and fraudulent acts as part of the Opioid Supply Chain Enterprise, that furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents that the Supply Chain Defendants were required to make, keep and/or file. Furthermore, the Supply Chain Defendants engaged in systematic and fraudulent acts as part of the Opioid Supply Chain Enterprise that were intended to and actually did utilize the mail and wire

facilities of the United States and Ohio, including refusing to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.

308. Through the Supply Chain Defendants' scheme, members of the Opioid Supply Chain Enterprise misrepresented that they were complying with their duties under the CSA, furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents, engaged in unlawful sales of painkillers that resulted in diversion of controlled substances through suspicious orders, and refused to identify or report suspicious orders of controlled substances sales to the DEA. Defendants' refusal to report suspicious orders resulted in artificial and illegal increases in the annual production quotas for opioids allowed by the DEA. The end result of the Supply Chain Defendants' fraudulent scheme and common purpose was continually increasing quotas that generated obscene profits and, in turn, fueled an opioid epidemic.

309. In particular, each of the Supply Chain Defendants were associated with, and conducted or participated in, the affairs of the Opioid Supply Chain Enterprise, whose common purpose was to fraudulently increase the quotas of prescription opioids so as to increase the quantity they could distribute.

310. The success of the Supply Chain Defendants' scheme allowed them to unlawfully increase and/or maintain high production quotas and, as a direct result, allowed them to make billions from the unlawful sale and diversion of opioids.

B. Impact of The Opioid Supply Chain Enterprise

311. The factual allegations and tragic statistics of injury and damage set forth above apply equally here.

C. Injury Caused and Relief Sought

312. The Supply Chain Defendants' violations of law and their pattern of corrupt activity directly and indirectly caused the County's injury. Their pattern of corrupt activity logically, substantially and foreseeably caused an opioid epidemic. The County's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as the County alleges, Defendants knew that the opioids were going to fuel and ever-increasing illicit prescription market, as well as increasing addiction and death as a result of licit prescriptions of opioids to treat chronic, long-term pain.

313. It was foreseeable and expected that flooding the illegal market for opioids would lead to a nationwide opioid epidemic. It was also foreseeable and expected that it would lead to increased opioid addiction and overdose. The County's injury was logically, foreseeable, and substantially caused by the opioid epidemic that the Supply Chain Defendants created.

314. Specifically, the Supply Chain Defendants' pattern of corrupt activity caused the opioid epidemic which has injured the County in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

315. The County's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for the County's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on the County's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Montgomery County;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

Count IV
Negligence
(Against All Defendants)
(Brought by the County of Montgomery Board of Commissioners, the Plaintiff in this Count)

316. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

317. Defendants owed the County a duty, including a preexisting duty, to not expose Plaintiff to an unreasonable risk of harm.

318. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in selling and/or distributing opioids.

319. Defendants had a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and their implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

320. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in distributing and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility *vis a vis* the County. Their duty cannot be delegated.

321. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

322. Defendants breached their duty to the County by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

323. The County does not allege that Defendants were negligent for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to the County.

324. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the distribution and sale of their prescription opioids.

325. Defendants were negligent by distributing and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to the County.

326. The method by which Defendants created this market was by distributing and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

327. A reasonably prudent opioid distributor should have anticipated an injury to the County as a probable result of distributing and selling prescription opioids in this manner.

328. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to the County as described herein.

329. Defendants had control over their conduct in Montgomery County. Each of the Defendants controlled the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their

employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

330. Because of each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

331. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

332. Defendants are in the business of selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

333. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the County – exactly as would be expected when medical grade heroin in the form of prescription opioids flood the community and are diverted into an illegal, secondary market.

334. Reasonably prudent distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of R.C. § 4729.35 and Ohio Administrative Code §§ 4729-9-12, 4729-9-

16, and 4729-9-28, as well as a violation of 21 U.S.C. § 823, and 21 C.F.R. § 1301.74 for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

335. Defendants conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); and Ohio law, including, but not limited to, R.C. § 2925.02(A); and § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28. The County was a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to the County.

336. Defendants also violated federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

337. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, the County has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

338. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, the County has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

339. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the public.

340. Defendants' misconduct alleged in this case is ongoing and persistent.

341. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

342. The County has incurred expenditures for special programs over and above its ordinary public services.

343. The County has suffered an indivisible injury as a result of the tortious conduct of Defendants.

344. The tortious conduct of each Defendant was a substantial factor in producing harm to the County.

345. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

346. The County seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count V
Injury Through Criminal Acts
(R.C. 2307.60)
(Against All Defendants)
(Brought by the County of Montgomery Board of Commissioners, the Plaintiff in this Count)

347. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

348. R.C. § 2307.60(A)(1) provides that:

> Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law, may recover the costs of maintaining the civil action and attorney's fees if authorized by any provision of the Rules of Civil Procedure or another section of the Revised Code or under the common law of this state, and may recover punitive or exemplary damages if authorized by section 2315.21 or another section of the Revised Code.

349. In the distribution and sale of opioids in Montgomery County, Defendants violated R.C. § 2925.02(A), which states:

> No person shall knowingly do any of the following:
>
> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent.

350. Through the Defendants' actions as described in this Complaint, including flooding the market with opioids, deliberately disregarding their obligations to maintain effective controls against diversion, Defendants furnished to residents of the County or induced or caused residents of Montgomery County to use a controlled substance, thereby causing serious physical harm to those persons and causing them to become drug dependent, in violation of R.C. §§ 2925.02(A)(3).

351. The exemption in R.C. § 2925.02 only applies to drug distributors when their "conduct is in accordance with Chapters R.C. § 3719., 4715., 4723., 4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

352. In the distribution and sale of opioids in Ohio and Montgomery County, Defendants violated R.C. § 2925.02(A)(2), which makes it a crime to: "Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale by the offender or another person."

353. Defendants may claim an exemption to R.C. § 2925.03(A)(2) only if their "conduct is in accordance with Chapters 3719., 4715., 4723., 4729., 4730., 4731., and 4741. of the Revised Code." Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

354. Defendants have engaged in additional criminal acts detailed in the Ohio Corrupt Practices Act Count above, including acts of criminal wire fraud, mail fraud, telecommunications fraud, unlawful dealing in controlled substances, and violations of the Ohio Corrupt Practices Act.

355. It was foreseeable to Defendants that their misconduct alleged in this Count would lead to addiction, abuse, misuse, and diversion of opioids, both in Montgomery County and throughout the United States.

356. The County was within the zone of interest protected by these criminal laws.

357. As a direct and proximate result of Defendants' criminal acts as described in this Count, the County suffered injury and damages, for which it is entitled to recover pursuant to R.C. § 2307.60(A)(1).

358. Defendants' misconduct alleged in this case is ongoing and persistent.

359. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

360. The County has incurred expenditures for special programs over and above its ordinary public services.

361. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

362. The County seeks all legal relief to which it may be entitled pursuant to R.C. § 2307.60(A)(1), including *inter alia* compensatory damages, punitive and/or exemplary damages, attorney's fees, and the costs and expenses of suit, including pre- and post-judgment interest.

Count VI
Unjust Enrichment
(Against All Defendants)
(Brought by the County of Montgomery Board of Commissioners, the Plaintiff in this Count)

363. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

364. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the County, including from opioids foreseeably and deliberately diverted within and into Montgomery County.

365. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

366. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

367. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

368. These expenditures have helped sustain Defendants' businesses.

369. The County has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

370. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

371. The County has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products.

372. Defendants have unjustly retained benefits to the detriment of the County, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

373. Defendants' misconduct alleged in this case is ongoing and persistent.

374. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

375. The County has incurred expenditures for special programs over and above its ordinary public services.

376. The County seeks an order compelling Defendants to disgorge all unjust enrichment to Plaintiff; and awarding such other, further, and different relief as this Honorable Court may deem just.

Count VII
Civil Conspiracy
(Against All Defendants)
(Brought by the County of Montgomery Board of Commissioners, the Plaintiff in this Count)

377. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

378. Defendants engaged in a civil conspiracy in their unlawful distribution of opioids into Montgomery County.

379. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

380. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, the claim under the Ohio Corrupt Practices Act. Such allegations are specifically incorporated herein.

381. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

382. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

383. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

384. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

385. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm.

386. Defendants' misconduct alleged in this case is ongoing and persistent.

387. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

388. The County has incurred expenditures for special programs over and above its ordinary public services.

389. The County seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, the County requests the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate the public nuisance;

D. A finding that, by the acts alleged herein, Defendants violated the Ohio Corrupt Practices Act ("OCPA"), R.C. 2923.31, *et seq.*;

E. A finding that, by the acts alleged herein, Defendants violated R.C. 2307.60;

F. An award of three times the County's actual damages under R.C. 2923.31, *et seq.*;

G. Compensatory damages in an amount in excess of $25,000 sufficient to fairly and completely compensate for all damages alleged herein;

H. Punitive damages in excess of $25,000;

I. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

J. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

K. For all other relief at law or in equity, deemed just by this Court.

Dated: July 25, 2018 Respectfully submitted,

/s/ Mathias H. Heck, Jr.

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JURY DEMAND

Plaintiff requests a jury be seated to try all issues of fact and law presented herein.

By: /s/ Mary E. Montgomery
Mary E. Montgomery, (0069694)